Comunicazioni orali

Structural interventions

C1

IMPACT OF MYOCARDIAL FIBROSIS IN MITRACLIP-TREATED PATIENTS: RESULTS FROM A MULTICENTER REGISTRY

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Introduction. Percutaneous edge to edge clip technique has become a feasible skill for the treatment of severe mitral regurgitation in patients with unacceptably high risk for traditional surgical repair or replacement. However, doubts remain regarding the correct patient selection and pre-procedural pathway. We aim to investigate the role of pre-procedural cardiac magnetic resonance (CMR) to predict post-procedural outcomes.

Methods. Among all consecutive patients undergoing MitraClip implantation between June 2014 and January 2020 at Padua University Hospital and Centro Cardiologico Monzino, we selected 22 of them for whom pre-procedural CMR was available. Patients were divided into two groups depending on the presence of late gadolinium enhancement on CMR images. Cardiovascular (CV) death and hospitalization for heart failure at 1-year follow-up was defined as primary endpoint. Left ventricular (LV) remodeling (defined as the percentage in LV end-systolic volume index reduction from baseline calculated at transthoracic echocardiography), in patients with pre-procedural LV dilatation, was considered as secondary endpoint.

Results. Myocardial fibrosis was present in 13 out of 22 patients (59%); of those, 12 (92%) presented ischemic LGE pattern. Significant differences in terms of mechanism of mitral regurgitation were found between groups, with a greater prevalence of functional mitral insufficiency in patients with LGE on CMR (p= 0.007). At 1-year follow-up, the primary outcome occurred in 4 patients (18%). The presence of myocardial fibrosis on CMR, did not predict primary clinical endpoint at univariate Cox regression analysis (11% in patients with transmural LGE versus 23%, HR 2.22, CI 0.23-21.4, p= 0.48; Figure 1). When considering the secondary endpoint, neither the presence nor the amount of myocardial fibrosis predicts the extent of reverse LV remodeling at linear regression analysis (p=0.17 and p=0.33, respectively). Furthermore, the presence of a reduced LV myocardial circumferential or radial strain seems to impact on LV remodeling (p=0.008 and p=0.003, respectively), while reduction in longitudinal strain seems not (p=0.12).

Conclusions. Among patients undergoing MitraClip implantation, LGE presence (particularly with ischemic pattern) detected by CMR does not predict long-term clinical outcomes or LV remodeling. Furthermore, the degree of LV remodeling seems to be correlated with radial and circumferential CMR strain. Further studies will be needed to confirm our results and evaluate more sensitive pre-procedural tests in order to detect diffuse myocardial fibrosis which could be implicated in poor post-procedural outcomes.

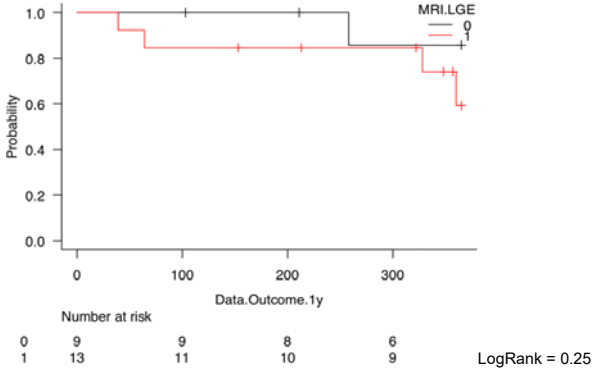

Figure 1. Kaplan-Meier plot according to the presence of myocardial fibrosis for 1-year clinical outcomes.

C2

CHRONIC KIDNEY DISEASE PREDICTS 5-YEAR ADVERSE OUTCOME IN PATIENTS WITH HEART FAILURE AND SECONDARY MITRAL REGURGITATION UNDERGOING PERCUTANEOUS MITRAL VALVE REPAIR WITH MITRACLIP

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Introduction. Chronic kidney disease (CKD) is strongly related to outcome in cardiovascular diseases. Limited data are available regarding the independent prognostic role of CKD after transcatheter mitral valve repair with MitraClip. We sought to evaluate the real impact of CKD in a large series of patients with heart failure (HF) and secondary mitral regurgitation (SMR) after MitraClip treatment.

Methods. The study included 565 patients with severe SMR from a multicenter international registry. Patients were stratified into three groups according to eGFR assessment before MitraClip implantation: normal eGFR (≥60 mL/min/1.73 m^2) (n =196), mild-to-moderate CKD (30-59 mL/min/1.73 m^2) (n = 267), and severe CKD (<30 mL/min/1.73 m^2) (n = 102). Primary endpoint was a composite of overall death and first re-hospitalization for HF, secondary endpoints were overall death, cardiac death and first re-hospitalization for HF.

Results. CKD was present in about two-thirds of patients. At 5-year Kaplan-Meier analysis, primary clinical endpoint occurred in 60% patients with normal eGFR, compared to 73% cases in mild-to-moderate CKD patients and 91% in severe CKD patients (p<0.001). Long-term overall death rate significantly decreased with increasing eGFR, as well as cardiac death and re-hospitalization for HF rates. Multivariate Cox-regression analysis identified severe CKD as the strongest independent predictor of adverse outcome (HR 2.136, 95% CI 1.164–3.918; p=0.014). Other independent negative prognostic factors were mild-to-moderate CKD, LVEF <30%, atrial fibrillation, diabetes mellitus and NYHA functional class.

Conclusions. CKD affected about two-thirds of patients undergoing MitraClip treatment for severe SMR, and it was a strong and independent predictor of 5-year adverse outcomes.

C3

SHORT-TERM OUTCOMES OF A NOVEL SELF-EXPANDING DEVICE: ITAL-NEO REGISTRY

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Introduzione. Il device di prima generazione prodotto dalla Boston Scientific per il trattamento trans-catetere della stenosi valvolare aortica (Acurate *neo*) ha dimostrato di associarsi ad un'incidenza non trascurabile di leak

paravalvolari "more-than-mild". Per tale motivo la compagnia produttrice, ha recentemente lanciato sul mercato internazionale la protesi di nuova generazione (Acurate *neo*2). Questa valvola sopra-anulare si caratterizza per la presenza di una gonna esterna più alta, in grado, teoricamente di ridurre l'incidenza di leak paravalvolari post-impianto emodinamicamente significativi. Allo stato attuale, non vi sono ancora evidenze circa l'utilizzo dell'Acurate *neo*2 in popolazioni real-world. L'ITAL-neo è un registro multicentrico, retrospettivo, osservazionale, investigator-initiated, che ha l'obiettivo principale di valutare la performance (in termini di sicurezza ed efficacia) dell'Acurate *neo*2 in una delle prime coorti real-world.

Metodi. Dal 30 settembre 2020 al 30 aprile 2021, presso 14 Centri Italiani, tutti i pazienti consecutivi affetti da stenosi valvolare aortica severa sintomatica trattati con Acurate *neo*2 attraverso approccio trans-catetere (TAVI), sono stati inclusi nel Registro. Criteri di esclusione sono stati gli interventi di valve-in-valve o le procedure eseguite attraverso un accesso diverso da quello trans-femorale o trans-succlavio. Sono stati raccolti i dati antropometrici, anamnestici, clinici, elettrocardiografici ed ecocardiografici prima della TAVI. Tutti i pazienti arruolati hanno eseguito una tomografia computerizzata (TC) toraco-addominale per il planning procedurale. L'outcome primario è stato definito in termini di raggiungimento del "device success" procedurale (secondo i criteri VARC-2). Gli outcomes intraospedalieri secondari comprendono: l'incidenza di leak paravalvolari "more-than-mild" alla valutazione ecocardiografica pre-dimissione, l'incidenza di complicanze maggiori quali sanguinamenti (secondo la definizione BARC-2), danni legati all'accesso vascolare (definizione VARC-2), impianto di pacemaker definitivo, ed infine la durata dell'ospedalizzazione. Il Registro prevede una fotografia del follow-up clinico ed ecocardiografico a 3 mesi dall'impianto.

Risultati. Sono stati inclusi 180 pazienti trattati con Acurate *neo*2. Di questi, i primi 95 sono stati oggetto dell'analisi ad interim di seguito riportata. La popolazione presentava un'età media di 81.9 anni, con una prevalenza del sesso femminile (72.6%) ed il 6.3% era portatore di pacemaker definitivo. L'STS-mortality era in media 4.59. Il 72.6% dei pazienti all'ECG pre-TAVI era in ritmo sinusale, in presenza di blocco atrioventricolare di I grado nel 20.2%. Il tasso di disturbi di conduzione intraventricolare pre-TAVI nei pazienti non portatori di pacemaker definitivo è stato osservato nel 17% dei casi. All'ecocardiogramma pre-procedurale sono emersi i seguenti parametri (valori medi): area valvolare 0.7 cm^2, gradiente medio 42 mmHg, frazione d'eiezione ventricolare sinistra 57.2%; nel 3.2% dei pazienti la valvola era bicuspide. Alla valutazione qualitativa della TC toraco-addominale il grado di calcificazione della valvulopatia è risultato lieve nel 48.4%, moderato nel 32.6% e severo nel restante 19% dei casi. Il 99.1% delle procedure è stato eseguito attraverso l'accesso trans-femorale, impiantando nel 44.2% una Acurate *neo*2 taglia M (24.2% taglia S e 31.6% taglia L). Il tasso di successo procedurale è stato raggiunto nel 97.9%, con soli due episodi di embolizzazione della protesi valvolare, entrambi adeguatamente trattatati attraverso il corretto posizionamento di una seconda protesi (valve-in-valve). Nella maggioranza dei pazienti (84.2%) prima del rilascio della protesi è stata eseguita una pre-dilatazione valvolare, mentre solo nel 29.5% si è reso necessario effettuare la post-dilatazione. Durante l'intera ospedalizzazione (mediana 6 giorni), non abbiamo osservato nessun caso di morte e/o infarto miocardico. Sono state registrate le seguenti incidenze di complicanze maggiori: sanguinamenti nel 3.2%, problemi vascolari nel 1.1%, stroke invalidanti nel 1.1%. Analizzando gli 89 pazienti non precedentemente sottoposti ad impianto di pacemaker definitivo, il 28.1% ha manifestato nel periodo post-impianto l'insorgenza di un nuovo disturbo di conduzione atrioventricolare avanzato e/o intraventricolare: di questi il 36% è andato incontro a risoluzione spontanea, mentre l'impianto di pacemaker definitivo è stato necessario nel 11.2%. Al controllo ecocardiografico pre-dimissione il gradiente trans-valvolare aortico è risultato 8.2 mmHg (valore medio) con una frazione d'eiezione ventricolare sinistra del 58.1%. La presenza di leak paravalvolari "more-than-mild" è stata osservata nel 3.1%, in assenza di leak severi; nel 56.9% dei pazienti è stato documentato la presenza di leak paravalvolare triviale o lieve.

Conclusioni. L'analisi ad-interim del Registro ITAL-neo dimostra l'efficacia e la sicurezza del device di nuova generazione Acurate *neo*2 nel setting della TAVI. Il successo peri-procedurale è risultato alto, a fronte di una bassa incidenza di complicanze maggiori. Le migliorie tecnologiche sono associate ad un basso tasso di leak paravalvolari emodinamicamente significativi (3.1%). Il non trascurabile tasso d'impianto di pacemaker definitivo, potrebbe essere dipeso dalla presenza di un'alta prevalenza di disturbi di conduzione pre-TAVI. Il Registro non è scevro da complicanze quali la natura retrospettiva, la discrezionalità del singolo operatore nella scelta del paziente e delle singole fasi procedurali e l'assenza di un cor-lab centralizzato. Ciononostante, il Registro ITAL-neo rappresenta una delle prime coorti real-world che attestino la performance dell'Acurate *neo*2.

Baseline characteristics	
Age (years), mean ± SD	81.9 ± 4.6
Female sex, n (%)	69 (72.6)
BMI kg/m^2, mean ± SD	26.8 ± 5.4
Arterial hypertension, n (%)	82 (86.3)
Diabetes mellitus, n (%)	24 (25.2)
Dyslipidemia, n (%)	54 (56.8)
Smoking history, n (%)	15 (15.8)
Active malignancy, n (%)	6 (6.3)
Glomerular filtration rate (ml/min), mean ± SD	56.2 ± 22.8
Significant coronary artery disease, n (%)	33 (34.7)
• Previous PCI, n (%)	28 (29.5)
• Previous CABG, n (%)	3 (3.2)
Previous permanent pacemaker, n (%)	6 (6.3)
Significant peripheral vascular disease, n (%)	10 (10.5)
Significant carotid artery disease, n (%)	8 (8.4)
History of atrial fibrillation, n (%)	33 (34.7)
Previous stroke or TIA, n (%)	11 (11.6)
COPD, n (%)	10 (10.5)
NYHA class >I, n (1%)	95 (100)
STS mortality score (%), mean ± SD	4.59 ± 3.16
Baseline ECG and echocardiographic characteristics	
Sinus rhythm, n (%)	69 (72.6)
First-degree atrioventricular block in SR pts, n (%)	14 (20.2)
Intraventricular conduction disturbances in pts w/o PM, n (%)	17 [19% (9% RBBB – 10% LBBB)]
LVEF (%), mean ± SD	57.2 ± 8.9
Tricuspid valve, n (%)	92 (96.8)
Bicuspid valve, n (%)	3 (3.2)
Aortic valve area (cm^2), mean ± SD	0.70 ± 0.14
Transaortic mean gradient (mmHg), mean ± SD	42.2 ± 12.5
Concomitant aortic regurgitation, n (%)	68 (71.5)
• Mild, n (%)	50 (52.6)
• Moderate, n (%)	17 (17.9)
• Severe, n (%)	1 (1)
Concomitant mitral regurgitation, n (%):	82 (86.3)
• Mild, n (%)	62 (65.2)
• Moderate, n (%)	18 (18.9)
• Severe, n (%)	2 (2.1)
Computed tomography analysis	
Annulus area (mm^2), mean ± SD	429.2 ± 57.8
Annulus perimeter (mm), mean ± SD	74.5 ± 5.0
SOV mean diameter (mm), mean ± SD	30.9 ± 2.8
STJ mean diameter (mm), mean ± SD	28.2 ± 2.8
LVOT mean diameter (mm), mean ± SD	23.0 ± 1.8
Left main height (mm), mean ± SD	13.6 ± 2.9
Right coronary artery height (mm), mean ± SD	16.5 ± 3.2
Aortic angle (°), mean ± SD	49.7 ± 9.8
Degree of leaflet calcification	
• Mild, n (%)	46 (48.4)
• Moderate, n (%)	31 (32.6)
• Severe, n (%)	18 (19)
Degree of annulus calcification	
• None, n (%)	61 (64.2)
• Mild, n (%)	26 (27.4)
• Moderate, n (%)	5 (5.2)
• Severe, n (%)	3 (3.2)
Degree of LVOT calcification	
• None, n (%)	77 (81)
• Mild, n (%)	15 (15.8)
• Moderate, n (%)	3 (3.2)
Procedural results	
Access route	
• Trans-femoral, n (%)	94 (99.1)
• Trans-subclavian, n (%)	1 (0.9)
Acurate neo2 size	
• S, n (%)	23 (24.2)
• M, n (%)	42 (44.2)
• L, n (%)	30 (31.6)
Valve pre-dilatation, n (%)	80 (84.2)
THV post-dilatation, n (%)	28 (29.5)
Implantation depth (mm), mean ± SD	4.51 ± 1.62
Concomitant angio and/or PCI, n (%)	36 (37.9)
Procedure length (min), mean ± SD	96.2 ± 33.5
Fluoroscopy time (min), mean ± SD	23.5 ± 9.5
Contrast dye amount (ml), mean ± SD	126.3 ± 60.3
Antithrombotic therapy	
• Single antiplatelet, n (%)	36 (37.9)
• Dual antiplatelet, n (%)	23 (24.2)
• Oral anticoagulant, n (%)	27 (28.4)
• SAPT+OAC, n (%)	8 (8.4)
• DAPT+OAC, n (%)	1 (1.1)
Pre-discharge echocardiographic results	
LVEF (%), mean ± SD	58.1 ± 8.3
Transaortic mean gradient (mmHg), mean ± SD	8.2 ± 3.6
Transaortic max gradient (mmHg), mean ± SD	14.8 ± 6.4
Aortic valve area (cm^2), mean ± SD	1.81 ± 0.48
Prosthesis-patient mismatch (36 pts)	
• Insignificant (>0.85 cm^2/m^2), n (%)	28 (77.7)
• Moderate (<0.85 and >0.65 cm^2/m^2), n (%)	8 (22.3)
• Severe (<0.65 cm^2/m^2), n (%)	0 (0)
Residual paravalvular leak:	
• None, n (%)	38 (40)
• Mild, n (%)	54 (56.9)
• Moderate, n (%)	3 (3.1)
• Severe, n (%)	0 (0)

C4

CONTRAST-INDUCED NEPHROPATHY IN PATIENTS UNDERGOING STAGED VERSUS CONCOMITANT TAVI AND CORONARY PROCEDURES

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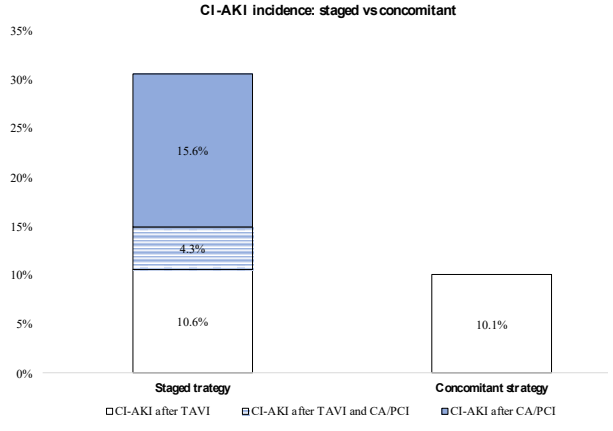
Introduction. The impact of staged versus concomitant coronary procedures on renal function in patients with aortic stenosis undergoing transcatheter aortic valve implantation (TAVI) remains unclear.

Methods. Patients undergoing CA/PCI one week up to 4 months before TAVI (staged strategy), or during the same TAVI procedure (concomitant strategy), were retrospectively analyzed in terms of baseline, procedural characteristics and kidney function, both pre-and post-procedure. Thirty-day follow-up data after TAVI were collected to assess the early safety outcomes of TAVI procedures as well as long term kidney function.

Results. A total of 339 patients undergoing coronary procedures and TAVI as a staged strategy (160, 47.2%) or concomitant strategy (179, 52.8%) were analyzed. CI-AKI occurred in 49 patients in the staged strategy group (30.6%) and in 18 patients (10.1%) in the concomitant strategy group (p<0.001). Among the staged strategy group, 25 (15.6%) patients developed CI-AKI after CA/PCI, 17 (10.6%) after TAVI, and 7 (4.3%) after both the procedures. Staged strategy was associated with a higher risk of CI-AKI (OR 3.948; p<0.001) after adjustment for multiple confounders and regardless of the baseline renal function (p for interaction=0.4) when compared with the concomitant strategy. At a median follow-up of 24.0 months (3.0-35.3), CI-AKI was not associated with sustained renal injury (p=0.794), irrespectively of the adopted strategy. The concomitant strategy did not impact the overall early safety at 30-day follow-up after TAVI compared to the staged strategy (p=0.609).

Conclusions. Performing coronary procedures with a staged strategy before TAVI was associated with a higher risk of CI-AKI compared with a concomitant strategy. Moreover, a concomitant strategy did not increase the risk of procedure-related complications.



C5

TRANSCATHETER MITRAL VALVE-IN-VALVE AND VALVE-IN-RING REPLACEMENT: A SINGLE CENTRE EXPERIENCE

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Introduction. Transcatheter mitral valve-in-valve (ViV) and valve-in-ring (ViR) are emerging techniques for high surgical risk patients presenting with degenerated bioprostheses or failed rings, although limited data are available. The aim of this study is to describe the clinical and echocardiographic outcomes of patients treated at our centre and to compare their outcomes according to the treatment received (ViV vs. ViR).

Methods. All consecutive patients treated at San Raffaele Hospital between January 2010 (beginning of the percutaneous mitral valve program) and October 2020 were enrolled in this retrospective registry. The pre-specified primary endpoint was 30 days and 1-year mortality, and the pre-specified secondary endpoint was technical, device, and procedural success (defined according to the MVARC criteria). We analysed data collected in all patients and after stratification according to the treatment received (ViV vs. ViR).

Results. A total of 56 patients (44 ViV and 12 ViR) with median age of 80.5 (75.5 – 85) years and mean Society of Thoracic Surgeons (STS) score of 7.2% were enrolled. The baseline mean trans-mitral gradient was 11.8±7.4 mmHg and 89% of patients presented moderate or greater mitral regurgitation, with no differences between ViV and ViR. 76% of patients presented in NYHA class III or IV, without significant differences between the two groups. Overall, the procedure was carried out through the trans-septal approach in 66% of cases; prostheses implanted included all Sapien series of valves and Myval. Overall, technical and device success rates were 89% and 80%, respectively. However, compared with the ViV group, the ViR group showed lower technical success rate (75% vs. 100%; p=0.001) due to more frequent conversion to surgery (0% vs 8%; p=0.05) and need for second valve implantation (0% vs. 25%; p=0.003). Procedural success rate was 85%, with a not significant tendency towards better results in ViV (88 vs. 75%). At discharge, 91% of patients received oral anticoagulation for at least 3-6 months, while 4% and 2% received additional SAPT or DAPT due to comorbidities. At 1-year follow-up, all-cause death occurred in 11% of cases and 70% of patients were in NYHA Class 1-2, without significant differences between the two groups. 30 days echocardiographic follow up revealed a significant reduction in the mean trans-mitral gradient in both groups (from 12 to 6mmHg), but residual moderate/severe mitral regurgitation was more frequently observed in the ViV group (4.4 vs. 25%, p=0.06).

Conclusions. Our single centre experience showed favourable outcomes of trans-catheter ViV and ViR in high-risk patients with degenerated bio-prostheses or failed annuloplasty rings, both in terms of safety and efficacy. ViR was associated with lower technical success rate, and further studies are warranted to understand the mechanism of failure in this subset. The majority of patients were treated with anticoagulation therapy at discharge and no thrombotic events were observed at 1-year follow-up.

C6

REAL-WORLD EXPERIENCE WITH A LARGE BORE VASCULAR CLOSURE DEVICE DURING TAVI PROCEDURE: EARLY OUTCOMES AND PREDICTORS OF FAILURE

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Background. Peri-procedural vascular and bleeding complications increase morbidity and mortality in transfemoral transcatheter aortic valve implantation (TF-TAVI) patients. To face this problem, several vascular closer devices (VCDs) have been developed. Among them, the novel collagen plug-based Manta VCD (Essential Medical Inc, Exton, PA) is the only one designed for large bore percutaneous access closure; however, data regarding related outcomes are scant.

Aims. To assess safety and efficacy of Manta VCD and to detect possible predictors of vascular access closure failure after placement in an unselected TAVI-TF population.

Methods. A prospective observational cohort of all-comers consecutive patients undergoing 18-Fr Manta VCD deployment following TAVI has been identified. Procedures were performed in Padua Hospital from September 2019 to October 2020. According to Valve Academic Research Consortium-2 (VARC-2) definitions, in-hospital outcomes were collected to evaluate early performance of the study device; moreover, logistic regression and the Youden's index were used to identify baseline and periprocedural characteristics related to Manta-access vascular complications.

Results. 88 TF-TAVI patients (median age 82 years, 48% male) were included in our analysis. A balloon-expandable valve was implanted in 43% of cases and 57% of patients were treated with self-expandable devices, with a median size of sheath introducer of 14 Fr [IQR 14, 16]. The technical success rate after Manta implantation was 90% (n=79) in the overall population, reaching 97% rate after the first 30 patients (early learning phase). No in-hospital death occurred. None of the patients experienced VARC-2 major vascular and major bleeding Manta-access related vascular complications. Minor VARC-2 events rate was 11%, including 7 occlusions, 2 ruptures and 1 dissection all successfully managed during index procedure without other clinical sequelae. Independent predictors of Manta VSD failure were age (p=0.023), a lower minimal artery diameter at common femoral artery (CFA) (p<0.01) as well as a lower Manta-access puncture distance from femoral bifurcation (p=0.033). In particular, a threshold value of CFA diameter of 7.10 mm (AUC 0.91) seemed to predict the worst Manta performance as well as a value of the puncture distance from the femoral bifurcation <1.0 mm (AUC 0.64). The presence of calcification at the puncture site and the sheath size seemed to not affect early VSD performance.

Conclusion. These early all-comers experience with Manta large bore access VCD during TF-TAVI procedures showed a reassuring rate of vascular complications. Higher age, lower vessel size and lower distance of the access puncture to CFA bifurcation were identified as predictors of Manta-access vascular closure failure.

C7

SAFETY OF SINGLE ANTIPLATELET THERAPY FOR THE FIRST 6 MONTHS AFTER PERCUTANEOUS PATENT FORAMEN OVALE CLOSURE

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Introduction. The best antiplatelet treatment, ie single vs dual one, is not well established in the early period after percutaneous patent foramen ovale (PFO) closure. We analysed the safety of only single antiplatelet therapy for the first 6 months after PFO closure.
Methods. Between 1999 and 2021, all the 980 consecutive patients undergoing transcatheter PFO closure with Amplatzer devices for any reason at our Institution were included in a registry. Usually, we administer only single antiplatelet therapy in the first 6 months after closure. Baseline, in-hospital and 6-months features were analyzed as well as major adverse events (MAE) such us death, ischemic events and device thrombosis.
Results. Nowadays, 6-month follow-up was completed in 637 patients. Women were 56% and mean age was 49 years old. The indication to closure was cryptogenic embolism in 83% of the cases (97.5% cerebral, 2% peripheral, 0.5% combined). Several patients had multiple risk factors including atrial septal aneurysm. No MAE occurred during the procedure and hospital stay. In this early period, 597 patients (94%) received only single antiplatelet therapy, the remaining 6% underwent dual antiplatelet therapy for 3 months (and thereafter single one) or anticoagulation. At 6 months, the rate of MAE was very low in absence of cardiac death and ischemic events. Only 1 patient suffered for asymptomatic device thrombosis requiring switch to successful anticoagulation. These results are in line with literature data on dual antiplatelet treatment in the same context. Enrollment is ongoing and extended data will be presented.
Conclusions. Our registry suggested a great safety of only single antiplatelet therapy in the first 6 months after PFO closure with Amplatzer devices with very low rate of MAE and only one asymptomatic device thrombosis.

C8

REAL-WORLD EXPERIENCE WITH THE NEW WATCHMAN FLX DEVICE: DATA FROM TWO HIGH-VOLUME SICILIAN CENTERS. THE FLX-iEST REGISTRY

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Introduction. Left atrial appendage closure (LAAC) represents a standard therapy for patients with atrial fibrillation and contraindication to oral anticoagulation (OAC). The "Watchman FLX" presented innovative features: higher conformability to LAA shapes, reduced length of the device, closed "atraumatic" distal end with "flex-ball" shape during deployment, flattened covered external surface. We report the early real-world experience with the innovative Watchman-FLX device, in two centers at high-procedural volume with consolidated LAAC experience.
Methods. From May 2019 to January 2021, we enrolled 200 consecutive patients treated with Watchman FLX in a non-randomized double-center registry. We collected procedural data and followed up the patients for mid-term clinical outcomes.
Results. Mean age was 77±7.18 years (67.5% male). Patients presented Hypertension in 93% of cases, CKD in 57.5% (mean creatinine level 2±1.1), Diabetes mellitus in 41.5%, Coronary artery disease and Heart failure in 55%. 29% had previous stroke and 56.5 bleeding events. Mean CHA2DS2-VASc was 5±1.40 and HAS-BLED 4±1.01. LAAC indication was: 39.5% of cases symptomatic hemorrhage, 39% need for Triple antithrombotic therapy, 32% gastro-intestinal bleeding; 18% of patients presented OAC intolerance. TEE guidance was feasible in 186 cases (93%), of which 96 (48%) in general anesthesia and 90 (45%) in conscious sedation (MID-DEX) protocol. 14 ICE cases (7%) were performed in local anesthesia. FLX device repositioning after first attempt was required in 40 cases (20%) without any complication. Device size change, after first choice was needed in 8 cases (4%). In one exceptional case simultaneous implant of 2 Watchman FLX devices was performed in a bi-lobed LAA. Peri-device leak was found in 2 cases (1%), 1 solved by changing FLX size (31 to 35 mm). Final procedural success was 99.5%; 1 unsuccessful case due to LAA reverse chicken-wing with very short depth; no device embolization. 6 complications were related to access-site (3%), 2 cases of combined LAAC-Mitraclip procedure; 2 major bleedings occurred and 1 in-hospital death due to hemorrhagic shock (HAS-BLED = 6). At mean follow-up of 272±172.76 days, only 2% of (non-device-related) stroke and 0.6% fatal bleeding resulted.
Conclusion. Our registry in a high-risk population treated with the innovative Watchman FLX device, showed high technical procedural success with easy implant and repositioning, no embolization, good LAA sealing and low rate of ischemic/bleeding complications.

Complex PCI: devices and technique

C9

EXCIMER LASER-BASED "EXPLOSION TECHNIQUE" FOR THE TREATMENT OF CORONARY CALCIFIED LESIONS: THE EXPLOIT REGISTRY

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Introduction. The importance of good lesion preparation and debulking especially in calcified coronary lesions is crucial in order to prevent serious adverse events due to stent underexpansion. The Excimer Laser Coronary Atherectomy (ELCA) has been shown to represent one of the currently available tools able to effectively treat calcified plaques. The use of contrast injection at the highest fluency (80 mJ/mm^2 and 80Hz for the 0.9 mm catheter) during ELCA-based angioplasty, the so called "explosion technique", seems to be crucial to amplify the energy and the shock waves in order to dilate complex calcified lesions. The EXPLOIT Registry sought to evaluate the safety and the effectiveness of the ECLA-based "explosion technique" for the treatment of highly calcified complex coronary lesions.
Methods. From January 2019 to January 2020, 79 patients were enrolled from eight different centers. The whole spectrum of clinical presentations was represented and only patients presenting with highly calcified coronary lesions were included. All the lesions were treated using contrast injection and the highest fluency (80 mJ/mm^2 and 80 Hz for the 0.9 mm catheter) during laser angioplasty. The primary endpoint was procedural success defined as <40% residual stenosis after laser. Secondary endpoints were major adverse cardiac events (MACE) including cardiovascular death, myocardial infarction (MI) and target lesion revascularization (TLR).
Results. The mean age of the patients was 69.4 ± 12 years old; 56% were male. A total of 98 lesions were treated, with a mean diameter stenosis of 84.4 ± 14.3%. The lesion length was 14.6 ± 6.9 mm, the mean vessel reference diameter was 2.8 ± 0.6 mm while the left anterior descending coronary artery (LAD) was the target vessel in 45% of cases. Seventy-seven lesions (78%) were found to be unbreakable with common conventional angioplasty balloons (balloon failure) and 22% of lesions (21 lesions), were found to be non-crossable with common conventional angioplasty balloons. The average number of laser runs was 4.18. Procedural success was obtained in 93 lesion (94.8%). No adverse event was reported at discharge. The one-year follow-up was available for 63 (80%) patients; 4 (5%) patients were re-hospitalized for MI and in two cases (2.5%) TLR occurred.
Conclusions. In the multicenter EXPLOIT Registry, the ELCA-based "explosion technique" has shown to be safe and effective for the treatment of a wide spectrum of complex coronary calcified lesions.

C10

IMMEDIATE VERSUS STAGED COMPLETE REVASCULARIZATION IN A REAL-WORLD COHORT OF PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION AND MULTIVESSEL DISEASE: INSIGHTS FROM THE SPUM-ACS REGISTRY

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Introduction. Complete revascularization (CR) with percutaneous coronary intervention (PCI) as compared with infarcted-related artery (IRA)-only in patients with ST-elevation myocardial infarction (STEMI) and multivessel disease (MVD) has been consistently associated with lower risk of major adverse cardiac events (MACE). Whether CR should be performed in single or multi-stage procedures is still debated.

Methods. We sought to assess among a real-word ACS population enrolled in the prospective multi-center Special-Program-University-Medicine (SPUM, NCT01000701) the impact of staged CR (sCR) on 1-year MACE (myocardial infarction, stroke and all-cause mortality). MVD was defined s significant stenosis (>70%) in two or more major epicardial coronary arteries. A multivariate analysis including independent predictors of MACE, selected by simplifying the overall logistic regression of long-term outcomes using the stepwise backward selection was performed.

Results. Out of 2,168 ACS-patients, 333 (15.4%) had STEMI with MVD; of these 217 (65.2%) underwent sCR. sCR patients were overall younger (age ≥75 years 17.5% vs 25.9%; p=0.05), with higher LDL-cholesterol levels (3.7±1.2 vs 3.2±1.0 mmol/l; p<0.001) and mildly reduced left ventricular ejection fraction (LVEF 49.0±10.0 vs 45.6±12.6%, p=0.022) compared to those treated with iCR, who presented with a more complex CV disease burden (previous CABG 10.3% vs 1.4%, p<0.001). Patients who underwent sCR had lower rates of MACE at 1 year, compared to those subjected to iCR (2.3% vs 8.6%, p=0.01), which persisted after adjusting for baseline differences (adjusted HR 0.32, 95% CI: 0.11-0.93, p=0.04). No statistically significant differences were found as regards acute renal failure (AKI 2.3% vs 2.6%, p=0.57) or unplanned revascularization (UR 5.5% vs 7.8%, p=0.28). At multivariate analysis age ≥75 years and hypercholesterolemia remained predictor of MACE, after stepwise backward analysis.

Conclusions. In real-word ACS patients with STEMI and MVD, sCR is associated with a lower rate of MACE compared to iCR, without differences in term of AKI or TLR. These data have to be confirmed in larger and dedicated trials.

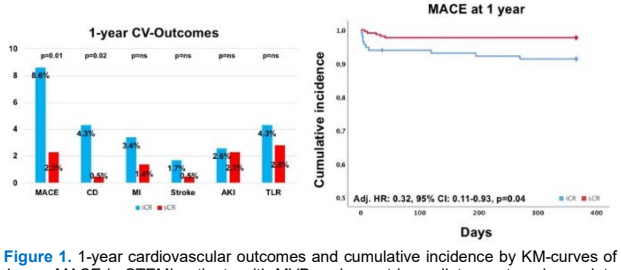

Figure 1. 1-year cardiovascular outcomes and cumulative incidence by KM-curves of 1-year MACE in STEMI patients with MVD underwent immediate vs staged complete revascularization.
MACE, major adverse cardiac events; CD, cardiac death; MI, myocardial infarction; AKI, acute kidney failure; TLR, target lesion revascularization.

C11

SAFETY AND FEASIBILITY OF NON-INVASIVE MECHANICAL VENTILATION IN THE CATHLAB IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION AND ACUTE DECOMPENSATED HEART FAILURE UNDERGOING PERCUTANEOUS CORONARY INTERVENTION

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Background. Non-invasive ventilation with continuous positive airway pressure (CPAP) is an established treatment for acute decompensated heart failure (ADHF). The aim of the present analysis was to evaluate safety and feasibility of continuous positive airway pressure (CPAP) in patients with acute myocardial infarction (AMI) and ADHF, undergoing percutaneous coronary intervention (PCI).

Methods. All consecutive patients admitted for AMI, receiving CPAP for ADHF in the CathLab during PCI were retrospectively included. The main study endpoints were safety and feasibility of CPAP.

Results. Between December 2018 and March 2021, 25 patients were included; median age was 78 (IQR 70-86) yrs, 12 (48%) were females, 16 (64%) presented with ST elevation myocardial infarction (STEMI), and 13 (69%) were in cardiogenic shock. At admission, median ejection fraction was 35 ± 10%, with 8 (32%) patients showing severe mitral regurgitation, mean PaO_2/FiO_2 was 183 (IQR 141-261), mean lactate level was 2.4 (IQR 1.3-3.8) mmol/L, and N-terminal pro B-type natriuretic peptide 9454 (IQR 4588-27036) ng/L. CPAP was set with a median FiO2 of 53 ± 13% with a PEEP of 7.5 ± 2 mmHg. CPAP was well tolerated in 22 patients (88%), 3 (12%) patients interrupted the treatment for interface intolerance, not due to hemodynamic deterioration. Notably, in all cases CPAP was managed by nurses of the CathLab, without the routinary need for the anesthetist. The latter intervened only in 4 (16%) cases, due to cardiac arrest in one case and to sedate the patients in 3 cases. In no case orotracheal intervention was necessary during the procedure. In patients who well tolerated non-invasive ventilation (88%), CPAP was associated to a significant increase of arterial oxygen concentration (59 vs 114 mmHg, p<0.001), pO_2/FiO_2 (183 vs 230, p=0.007), and a lower lactate concentration (2.4 to 1.5 mmol/L, p=0.002). One patient died in-hospital due to underlying disease, unrelated to study procedure.

Conclusion. CPAP during PCI in patients with AMI and ADHF seems safe and feasible. Larger studies are warranted to confirm these results.

C12

CORONARY REVASCULARIZATION ASSOCIATED WITH THERAPEUTIC HYPOTHERMIA IMPROVES OUTCOME OF COMATOSE PATIENTS RESUSCITATED FROM CARDIAC ARREST IRRESPECTIVE OF INITIAL RHYTHM AND ST-ELEVATION AT ROSC

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Background. Survival of comatose patients resuscitated after cardiac arrest (CA) is poor and influenced by both cardiovascular and cerebral recovery. An emergency protocol based on fast access to the catheterization laboratory and target temperature management (TTM) might improve patients outcome after return to spontaneous circulation (ROSC). However, controversy exists about the indication to fast coronary angiography in absence of transmural ischemia on electrocardiogram. We sought to evaluate the short and long-term outcome of patients undergoing TTM with systematic access to the catheterization laboratory, unless contraindicated, according to the local protocol.

Methods. We conducted a retrospective analysis of all consecutive comatose patients who underwent TTM after CA of presumed cardiac origin from September 2009 to March 2020. The neurological status was defined with the Cerebral Performance Category (CPC) scale.

Results. We enrolled 107 patients, with a mean age of 64 years. Eighty-two (76.6%) were males. CA had happened at home in 53 (49.5%) cases, public place in 34 (31.8%) or hospital/emergency room in 20 (18.7%). The initial rhythm was shockable, asystole or pulseless electrical activity respectively in 83 (77.6%), 9 (8.4) and 15 (14.0) patients. The median time to ROSC was 25 minutes. Etiology was STEMI in 56 (52%) NSTEMI in 17 (16%) or other. Overall, 102 (95.9) patients underwent coronary angiography and 1 coronary CT scan, whereas 66 (61.7) benefited from revascularization. Sixty-nine percent of those with initial shockable rhythm and 33% of non-shockable underwent percutaneous coronary angioplasty (PCI) of a culprit lesion. According to ECG at ROSC, PCI was needed in 88%, 36% and 19% of patients with ST-elevation, ST-depression or no-ischemia. In-hospital death was 29%. Sixty (56.0%) patients were discharged alive with CPC 1-2, 16 (15.0%) with CPC 3-4. Age, time CA-to-ROSC and culprit lesion PCI were independent predictors of in-hospital survival with good neurological status, while initial rhythm was not. Long-term survival of those presenting with a shockable rhythm was significantly higher than non-shockable, but PCI influenced positively survival irrespective of rhythm at presentation. Considering surviving patients discharged with CPC 1-2, those who had received PCI had higher 5-year survival that those without coronary revascularization.

Conclusions. Survival with good neurological status of comatose patients after CA may be improved by quick access to coronary angiography, PCI when indicated and TTM, suggesting that this approach may be of benefit even in patients without shockable rhythm at presentation or ST-segment elevation at ROSC.

Intracoronary imaging and physiology

C13

THE ROLE OF POST-PCI FUNCTIONAL EVALUATION: RETROSPECTIVE DATA FROM PROPHET-FFR REGISTRY (POST REVSCULARIZATION OPTIMIZATION AND PHYSIOLOGICAL EVALUATION OF INTERMEDIATE LESIONS: AN FFR-BASED SINGLE CENTER REGISTRY)

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Background. Invasive functional evaluation to guide revascularization of stable lesions is backed by a wide amount of evidences and it is endorsed by international guidelines with a class I recommendation[1]. Conversely, the role of FFR performed after PCI both to evaluate procedural results, to suggest the need of any optimization, as well as to predict patient outcomes, is strongly debated. Indeed, it is known that a significant stake of patients has evidence of residual ischemia or persistent symptoms long after the revascularization; most of the reasons for this phenomenon are related to procedural issues (stent expansion, malappositions, geographical miss, target lesion camouflage, possible damage to healthy nearby segments etc) and therefore could be theoretically corrected in a bid to improve outcomes[2-5]. The aim of the PROPHET-FFR registry is to provide a real-world description of the impact of post-PCI functional evaluation on patients outcomes.

Methods. This is a single-center observational study retrospectively enrolling patients requiring invasive functional evaluation to guide treatment, between January 2015 and June 2020. The prospective part of the study is still ongoing. Enrolled patients were divided in three groups: FFR negative patients (Group 1), patients with positive FFR undergoing PCI without post-revascularization assessment (Group 2), patients with positive FFR undergoing PCI and post-revascularization FFR reassessment (Group 3). Primary endpoint is the composite of cardiac death, spontaneous MI, target vessel failure (TVF).

Results. A total of 1556 patients were retrospectively enrolled, of which 1326 have a valid follow-up for a total of 1612 lesions. Post-PCI functional evaluation was performed in 158 patients (11,9%) and 167 lesions (10,3%) while 273 patients (20,5%) and 291 lesions (18%) received a functional guided PCI without post-revascularization assessment. The remaining 895 patients (67,4%) and 1154 lesions (71,5%) were deferred for negative functional tests. 59 lesions had the first FFR after PCI below 0,9, in 12 cases further optimization was performed and in 7 of these cases a new FFR was carried out. Average final FFR was 0.9 ± 0.05. Median follow-up is 21 months (IQR 15), being censured at the first event and within 36 months. A total of 128 events have been reported of which 73 (8,2%) in group 1, 40 (14,7%) in group 2 and 15 (9,5%) in group 3 (p=0.006) without significant difference among groups 1-3 (p=1,0) and groups 2-3 (p=0,240). Spontaneous MI were respectively 24 (2.7%), 5 (1.8%), 3 (1.9%) (p=0.656),cardiac deaths 16 (1.8%), 11 (4%) 3 (1.9%) (p=0.089), patient based TVF were 47 (5,3%), 26 (9,5%) and 9 (5,7%) (p=0,036) with non significant difference among groups 1 and 3 (p=1.0) and groups 2 and 3 (p=0,335). A final FFR above 0.9 is a good predictor of MACE free survival.

Conclusions. These real world retrospective data suggest that patients who receive functional guided and optimized PCI have a nonsignificant trend toward a reduction in MACE with an event rate that is comparable to patients having a non flow limiting stenosis on preprocedural assessment. A final FFR value above 0.9 has a good specificity in predicting MACE free survival.

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C14

INCIDENCE, PREDICTORS AND PROGNOSTIC ROLE OF COMPLICATIONS OCCURRING DURING INTRACORONARY PROVOCATIVE TESTING WITH ACETYLCHOLINE IN PATIENTS WITH MYOCARDIAL ISCHEMIA AND NON-OBSTRUCTIVE CORONARY ARTERIES

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Background. Data on safety, predictors and prognostic role of complications during intracoronary provocative testing with acetylcholine (Ach) are scattered.

Methods. We prospectively enrolled patients undergoing intracoronary ACh provocative test for suspected myocardial ischaemia with angiographic evidence of non-obstructive coronary artery disease. Complications during the ACh test were collected. Major adverse cardiac events (MACE), arrhythmic events and angina status were assessed at follow-up.

Results. We enrolled 310 patients (mean age 60.6 ± 11.9; 169 [54.5%] chronic coronary syndromes [CCS] and 141 [45.5%] with myocardial infarction and non-obstructive coronary arteries [MINOCA]). The overall incidence of complications was low (9%) with a similar incidence in both settings (10 [7.1%] in MINOCA vs 18 [10.7%] in CCS, p=0.276). At multivariate logistic regression analysis, a previous history of paroxysmal atrial fibrillation (odds ratio [OR] 12.324, confidence interval [CI] 95% [4.641; 32.722], p=0.015) and moderate/severe diastolic dysfunction (OR 3.827, CI 95% [1.296; 11.304], p=0.015) were independent predictors for occurrence of complications. The occurrence of complications was not associated with a worse clinical outcome at follow-up in terms of both MACE, arrhythmic events and angina burden.

Conclusion. Intracoronary provocative testing with ACh test is safe in patients with myocardial ischemia and non-obstructive coronary arteries (including MINOCA patients), adding relevant information on the underlying pathogenic mechanism of ischemia. History of paroxysmal atrial fibrillation and moderate/severe diastolic dysfunction predicted complications during ACh test. However, occurrence of complications did not portend a worse prognosis at follow-up in terms of MACE, arrhythmic events and angina burden.

C15

OPTICAL COHERENCE TOMOGRAPHY PLAQUE MORPHOLOGY IN STABLE CORONARY ARTERY DISEASE: GENDER DIFFERENCES

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Introduction. Men and women with coronary artery disease (CAD) have significant differences in terms of clinical presentation and outcome. Whether such differences are due to clinical factors (age, risk factor pattern, comorbidities, etc.) or to specific atherosclerotic disease development is still unclear. Indeed, very few data from autoptic studies about differences in plaque morphology between sexes are available and data about intravascular imaging report contrast results about gender differences in plaque morphology.

The aim of this study is to investigate coronary plaque morphology, assessed by optical coherence tomography (OCT), looking at possible differences in plaque features between men and women.

Methods. We retrospectively collected and analyzed clinical data and coronary plaque morphology at OCT in men and women with stable CAD underwent to coronary angiography and OCT evaluation between February 2010 and January 2016 in our center. For all enrolled patients, clinical follow-up was obtained (as in-person visits, telephone interviews, and medical notes from any hospital admission or outpatient visits).

Results. Of the 237 plaques (from 136 patients) analyzed, 187 were in men and 50 in women. Mean age was equivalent between men and women (respectively 68±9 vs 69±9 years old, p=0.76). Baseline features were similar except for higher prevalence of active smoking (21% vs 3%, p=0.01), history of previous myocardial infarction (15% vs 3%, p= 0.05) and previous PCI (41% vs 19%, p=0.02) in men. As compared to men, OCT in women showed significantly smaller minimal lumen area (2,5 ± 1,0 mm^2 vs 3,2±1,7 mm^2, p=0.01), higher percent of area stenosis (63% ± 12 vs 60% ± 17, p=0.05) and longer lesion length (15 ± 9,0 mm vs 12 ± 6,2 mm, p=0,009). Furthermore, some significant differences were found in OCT plaque morphology between women and men. In particular the incidence of lipid rich plaques and macrophages infiltration were higher in women compared to men (70% vs 40%, p=0.03 and 56% vs 9%, p=0.003, respectively) (Figure 1). At multivariate analysis the female sex was the

only independent predictor of macrophages infiltration presence (p<0.0001), the female sex and the dyslipidemia were independent predictors of lipid rich plaques presence (p <0.0001 and p=0.002 respectively). At a mean follow-up of 6 years the incidence of major clinical events (all death, cardiovascular death, non fatal MI, new revascularization) was not different between women and men.
Conclusions. The results of our study suggest the hypothesis of gender-specific differences in atherosclerosis development. Women with stable coronary artery disease showed increased prevalence of adverse OCT features (macrophages infiltration and lipid rich plaque) compared to men. The greater vulnerability of coronary plaques in women seems independent from traditional risk factors for CAD and previous cardiovascular history. The findings of our study are hypothesis-generating and require specifically- designed studies to investigate gender-related differences in atherosclerosis development.

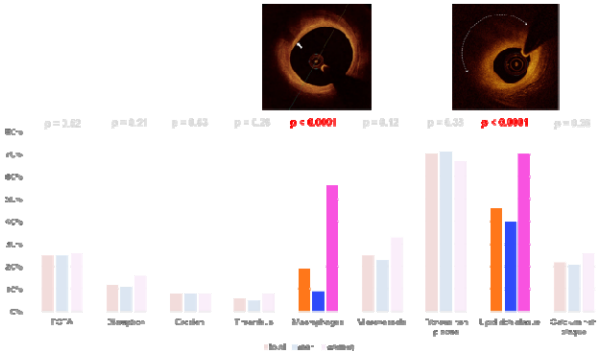

Figure 1. OCT morphological features of coronary plaques of men and women with stable CAD.

C16

CULPRIT PLAQUE MORPHOLOGY AND HEALING CAPACITY IN PATIENTS WITH AND WITHOUT PRE-INFARCTION ANGINA: AN OPTICAL COHERENCE TOMOGRAPHY IMAGING STUDY

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Introduction. The relationship between culprit plaque morphology, healed culprit plaques prevalence and clinical presentation of acute myocardial infarction (AMI) remains largely unexplored. We hypothesized that angina preceding the occurrence of AMI (pre-infarction angina, PIA) may reflect a distinct morphologic phenotype of culprit plaques and potentially different healing capacity.
Methods. We conducted a retrospective observational study in patients with AMI who underwent intracoronary optical coherence tomography (OCT) imaging of the culprit lesion before PCI at the Fondazione Policlinico A. Gemelli–Istituto di Ricovero e Cura a Carattere Scientifico (IRCCS), Rome. Based on the clinical history, patients were classified into 2 groups: (i) PIA group, defined as either intermittent chest pain within 6 hours preceding the final episode of chest pain, or unstable angina (or both) in the week preceding AMI; or (ii) no-PIA group, defined as a single episode of chest pain without prodromal symptoms in the preceding week. Culprit plaques were classified as plaque rupture (PR) or intact fibrous cap (IFC), and presence of layered appearance (healed plaque, HP) was assessed. Thrombus burden (TB) was estimated, and prevalence of diffuse calcification, neovascularization, and OCT-defined macrophage accumulation were evaluated.
Results. A total of 102 patients with AMI were included (50 PIA, 52 no-PIA). Patients with PIA showed a higher prevalence of IFC than PR (58% vs 42%, p=0.030). PR in patients with PIA were more frequently associated with macrophage accumulation (71.4% vs 28.6% p=0.001), and TB tended to be lower [22.0 (15.8–30.3) vs. 38.5 (12.8–67.5), p=0.145]. Diffuse calcifications were significantly less frequent in patients with PIA (22.0% vs. 40.4%, p=0.045), while neovascularization tended to be more frequent (58.0% vs. 42.3%, p=0.113). HPs prevalence was significantly higher in the PIA than in the no-PIA group (66.0% vs 25.0%, p<0.001).
Conclusions. Patients with PIA have a distinct culprit plaque phenotype, more frequently characterized by IFC and a relatively lower TB, with a significantly higher prevalence of plaque healing.

Miscellaneous

C17

CORRELATION BETWEEN HIGH TROPONIN LEVELS AND LEFT ATRIAL STRAIN AS BIOMARKERS OF INCREASED ATRIAL FIBRILLATION RATE IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION

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Introduction. Heart rhythm disorders, both bradyarrhythmias and tachyarrhythmias, are the most frequently observed complications in the acute phase and after primary angioplasty in patients with acute myocardial infarction (AMI). New onset atrial fibrillation (Afib) represents the most frequent arrhythmia occurring in 6% to 21% of patients with AMI and its onset increases the risk for thromboembolic events and all-cause mortality in these patients. Troponin levels measured with modern assays represent today the most specific cardiac biomarker of myocardial injury and its measurement represents the cornerstone for the diagnosis of AMI in accordance with the 2018 ESC Guidelines; however, also Afib itself causes an increase in troponin values (troponinopathy). Therefore, the single biohumoral value cannot assume prognostic value in helping the clinician to recognize patients with AMI who are more predisposed to develop Afib. So, the object of our evaluation was to support the elevated troponin values with echocardiographic biomarkers, such as the evaluation of left atrial strain (LAS), to perform a more accurate stratification of the arrhythmic risk in patients with AMI.
Methods. A prospective multiparametric study was carried out at our Interventional Cardiology Hub Center. 240 patients with ACS-STEMI diagnosed were recruited over one year from March 2020 to March 2021. Patients included were all ≥18 (55 ± 23 years), predominantly male (88% male, 12% female). Exclusion criteria were: permanent Afib; valvular heart disease (moderate or severe heart valve stenosis or valve replacement); implantation of a pacemaker or defibrillator; poor image quality. Emergency coronary angiography was performed to execute primary percutaneous intervention (primary PCI with DES) on the culprit vessel. All patients underwent echocardiography by GE Vivid 80 (GE Ultrasound, Horten, Norway) to evaluate changes in segmental kinetics, left ventricular ejection fraction. The ratio of peak early filling velocity (E) of mitral inflow to early diastolic annulus velocity (E') of the medial annulus (E/E') was calculated. Left atrial volume (LAVi, ml/m^2) and diameter were obtained through standard apical 4 and 2 chamber views with a frame-rate range of 40-71 frames/s; then, offline analysis of images was performed using EchoPAC version 201 (GE Vingmed Ultrasound) (VSSLV) software in order to calculate LAS for each one. Patients underwent serial sampling to evaluate temporally troponin values and the possible Afib appearance was recognized by telemetry monitoring. Statistical analysis was performed using SPSS version 20 (IBM, Armonk, New York), continuous variables were expressed as mean ± standard deviation (SD). Pearson's correlation coefficient was used to assess the correlation between strain value, baseline characteristics and troponin levels. All statistical tests were 2-sided, and a p-value of <0.05 was considered statistically significant.
Results. Two groups were identified: high troponin levels with pathological LAS and new Afib (m=47); medium-high troponin levels with normal LAS and no Afib (n=143). Respectively, LAS was 8.4 ± 4.0% vs. 16 ± 4.5%, p<0.001, LAVi 44 ± 5 ml/m^2 vs. 30 ± 3.2 ml/m^2, p=0.001, and peak of troponin levels 3.45 ± 0.46 ng/ml vs. 2.34 ± 0.22 ng/ml, p=0.002). Multivariate analysis identified that peak troponin levels alone were not a prognostic index of increased arrhythmic burden, while the correlation between high peak levels and altered LAS was an independent predictor of new AFib in AMI.
Conclusions. The evaluation of atrial dysfunction by new echo-derived parameters and its correlation with troponin values allows a more accurate stratification of arrhythmic risk in patients with ACS. The applicability of the obtained data would allow a more careful evaluation of the clinical trend and the prognostic outcome in the subcategory analyzed. Therefore, the association between biohumoral and instrumental parameters could become new biomarkers capable of predicting an increase in thromboembolic risk in AMI patients. The creation of an app that takes into account the parameters listed could be a possible future support that can help the clinician calculate the increased risk rate of new Afib in patients with ACS.

C18

EVALUATION OF BARC BLEEDINGS AND VASCULAR COMPLICATIONS IN PATIENTS UNDERGOING ULTRASOUND-GUIDED FEMORAL ARTERY PUNCTURE AND SUTURE-LIKE HEMOSTATIC DEVICE COMPARED TO TRADITIONAL FEMORAL PUNCTURE AND HEMOSTATIC TECHNIQUES. INSIGHTS FROM THE PETRONIO REGISTRY

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Objective. To evaluate the safety of a single and combined use of ultrasound-guided femoral puncture (U) and percutaneous arterial closure devices (P) in femoral artery procedures (FAP) compared to fluoroscopic guidance (F) and manual compression (M) in a large radial-focused interventional centre.

Background. U and P, taken individually, have improved safety in femoral arterial access procedures compared to traditional techniques.

Methods. All FAP performed between July 2017 and December 2018 in our centre were divided into three phases: (a) control period with F and M mainly performed; (b) phase out period where U and P were introduced; (C) intervention period where a 6-month expertise on the novel techniques was acquired. The overall population was further stratified into subgroups: F/M, U/M, F/P, U/P. The primary study endpoint was in-hospital access site bleeding events (BE) according to the BARC (Bleeding Academic Research Consortium) criteria. The secondary endpoint was vascular site complications (VASC).

Results. 418 procedures (14%) out of 3025 were performed via FA access during the study period. The overall access-site in-hospital BE were 97 (23%). Decreasing rates of BE (phase 1: n=46, 29%; phase 2: n=38, 22% e phase 3: n=13, 15%; p=0.027) (Figure 1) and VASC were observed during the three periods. BE occurred significantly more often in F/M group (F/M: n=48; 32%; U/M: n=12, 16%; F/P: n=18, 21%; U/P: n=19, 17%; p=0.008). F/M subgroup was an independent predictor of BE both in multivariable analysis and propensity score matching analysis.

Conclusions. The introduction of ultrasound-guided femoral puncture and percutaneous arterial closure devices has reduced access site bleeding with a progressive improvement after the first 6 months learning period.

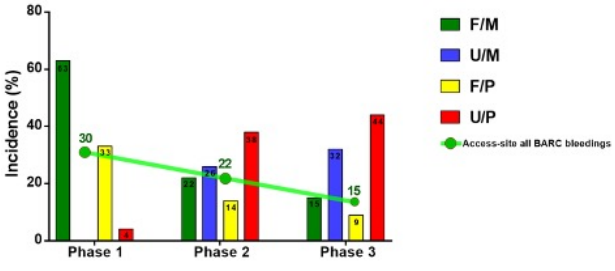

Figure 1. Trend of different femoral artery puncture/haemostasis approaches and BARC bleeding rates in the three study phases.
BARC, Bleeding Academic Research Consortium; F, fluoroscopic guided puncture; U, ultrasound guided puncture; M, manual compression; P, suture-like haemostatic device.

C19

"MOMA OPEN" TECHNIQUE FOR EMBOLIC PROTECTION DURING CAROTID ARTERY STENTING

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Introduction. Carotid artery stenting (CAS) represents an alternative option to surgical treatment for carotid artery stenosis. The recent technological advancements, like the development of new stent platform ("mesh stent") and the widespread use of embolic protection devices (EPD), have led to a reduction of risk of periprocedural stroke.

Methods. MoMa Ultra is a proximal cerebral protection device which prevent cerebral embolism by inflation of double balloon that provide temporary suspension of anterograde flow from the common carotid artery (CCA) and retrograde flow from the external common carotid artery (ECA). After the stent deployment, the removal of all sizes of debris is facilitated through aspiration. We develop a new method to utilize MoMa Ultra, called "MoMa Open Technique". After the inflation of double balloon in CCA and ECA, the system is kept open to allow continuous passive internal carotid artery flow reversal. During stent deployment and post-dilatation blood is removed and discharged continuously.

Results. A total of 194 patients referred for carotid artery stenting were systematically approached at our institution using the "MoMa Open technique". Mean age was 73.7 years (25% were octogenarians). Symptomatic patients were 40 (20.6%). The stent deployed was Mesh stent (Roadsaver or C-Guard, 130, 67.0%), Wallstent (37, 32.5%), "hybrid" stent (26, 13.4%) and "open cells" stent (1, 0.5%). Post-dilatation was performed in all patients. During the in-hospital period no clinical major adverse cardiac and cerebrovascular events were observed. In the immediate peri-procedural period 1 (0.5%) patient suffered a minor stroke. By 30 days post-implantation major stroke occurred in 3 (1.5%) and all-cause death in 2 (1.0%, 1 patient died by rupture of aortic abdominal aneurysm).

Conclusions. MoMa Open technique is feasible and is associated with very low rates of major cerebrovascular complications, especially during the immediate peri-procedural period.

C20

QUANTITATIVE FLOW RATIO FOR THE FUNCTIONAL ASSESSMENT OF EXTRACRANIAL INTERNAL CAROTID ARTERY STENOSIS

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Background. In asymptomatic patients at high surgical risk presenting with significant extracranial internal carotid artery stenoses, a selective invasive angiography is performed before carotid artery stenting (CAS). Sometimes, the angiographic findings of the stenosis could be discordant from those observed at the non-invasive imaging evaluation and the use of a pressure-wire to evaluate the hemodynamic potential of the stenosis, might be dangerous for the higher risk of cerebrovascular events.

Purpose. The quantitative flow ratio (QFR), by estimating the contrast flow velocity and based on a 3-dimensional quantitative angiography, might be of value as an online angiography-based functional assessment of internal carotid stenoses, in order to guide the physicians in the decision-making process to proceed or not to revascularization.

Methods. We prospectively enrolled 14 asymptomatic patients with an indication for invasive treatment of internal carotid artery stenosis. The echo-colour-Doppler was performed in 28 vessels and the Peak Systolic Velocity (PSV, cm/sec) was used to identify functionally significant stenoses (PSV >120 cm/sec). At the angiography, internal carotid artery stenosis degree was obtained according to NASCET criteria ($\%DS_{NASCET}$) and the lesion considered angiographically significant if >60%. After the exclusion of 4 vessels, QFR, area stenosis (AS, %) and minimal lumen area (MLA, mm^2) were obtained in the remaining 24 vessels.

Results. At the linear regression analysis, QFR values significantly correlated with PSV (r^2=0.71, p<0.001) as well as with $\%DS_{NASCET}$ (r^2=0.81, p<0.001). In addition, using the PSV as reference, QFR showed good accuracy to predict the presence of a functionally significant stenosis (AUC=1.00, p<0.001) with a cut-off value of 0.90. Similarly, the MLA significantly correlated with both the PSV and $\%DS_{NASCET}$ (r^2=0.61 and r^2=0.60, respectively, p<0.001) as well as the AS (r^2=0.68 and r^2=0.87, respectively, p<0.001).

Conclusion. This study suggests the possibility to adopt QFR for the functional assessment of extracranial internal carotid artery stenoses and should be considered as hypothesis generating to design a larger validation trial.